MOTION FILED
DEC 2 9 2003

(3)

No. 03-779

IN THE
Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

v.

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC., THE STOP & SHOP SUPERMARKET CO., WALGREEN CO., ECKERD CORP., CVS MERIDIAN, INC., AND RITE AID CORP., *ET AL.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

MOTION OF NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION AND BRIEF OF *AMICUS CURIAE* IN SUPPORT OF PETITIONER

MELVIN C. GARNER, PRESIDENT
DARBY & DARBY, PC
805 Third Avenue
New York, NY 10022
(212) 527-7717

DAVID F. RYAN
Counsel of Record
MATTHEW S. SEIDNER
FITZPATRICK, CELLA,
HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112
(212) 218-2100

Attorneys for Amicus Curiae

184977

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

The New York Intellectual Property Law Association ("NYIPLA") hereby moves, pursuant to Rule 37.2(b), for leave to file a brief *amicus curiae* in support of the petition for a writ of certiorari to the United States Court of Appeals for the Sixth Circuit. Petitioner and three of the six respondents have consented to the filing of this brief. We understand that the three remaining respondents have withheld their consent because they believe they are no longer interested parties.* A copy of the proposed *amicus* brief is attached.

As more fully explained at pages 1-4 of the attached brief under "Statement of Interest of *Amicus Curiae*", the NYIPLA is a professional association of more than 1,300 attorneys whose interests and practices lie in the area of patent, copyright, trademark, trade secret, and other intellectual property law. The NYIPLA is, accordingly, well positioned to address the questions presented from the perspective of litigators who counsel businesses that own, enforce and challenge patents, as plaintiffs and defendants in patent litigation — including litigation arising under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act").**

The NYIPLA seeks to file the proposed brief to describe unresolved issues arising from the split between the Sixth and Eleventh Circuits regarding the legality of payments made by innovator pharmaceutical companies to their generic

---

* Counsel for the NYIPLA made a first written request for consent on December 5, 2003 and repeated that request in writing on December 15, 2003. In response to those requests, the petitioner and three respondents consented in writing, and one respondent indicated by letter of December 16, 2003 that it no longer had an interest in the resolution of the case, but otherwise would have opposed the filing of the brief. We understand that the final two respondents oppose the filing of the brief, and also have stated that they are no longer interested parties.

** Pub. L. No. 98-417, 98 Stat. 1585 (1984).

company competitors in connection with the settlement of litigation arising under the Hatch-Waxman Act. The principal issue is whether a rule of reason analysis or a theory of *per se* illegality should govern the construction of such settlement terms.

In *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th 2003), *reh'g denied* (6th Cir. 2003), the Sixth Circuit held that such settlement payments were *per se* unlawful under the antitrust laws. In *Valley Drug. Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *reh'g denied*, (11th Cir. 2003), the Eleventh Circuit explicitly considered and rejected the Sixth Circuit's theory of *per se* illegality and held to the contrary that such provisions were presumptively lawful because they secured to the patentee no more than could have been obtained by enforcement of the patent in the settled litigation.

The far-reaching importance of this issue cannot be overstated. Many billions of dollars are at stake, and the current healthy pace of pharmaceutical innovation could be threatened if incentives to innovation are reduced. The NYIPLA respectfully submits that, as matters stand, infringement suits cannot be readily settled and its members and their clients are unable to interpret and apply the patent-antitrust precedents of this Court to avoid treble damages exposure. As representatives of intellectual property litigants, the NYIPLA believes that the issues faced by its members in counseling their clients who are considering the initiation or settlement of infringement actions must be resolved expeditiously.

It is respectfully requested that the Court grant leave to file the attached brief *amicus curiae* of the NYIPLA.

Respectfully submitted,

MELVIN C. GARNER, PRESIDENT
DARBY & DARBY, PC
805 Third Avenue
New York, NY 10022
(212) 527-7717

DAVID F. RYAN
Counsel of Record
MATTHEW S. SEIDNER
FITZPATRICK, CELLA,
HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112
(212) 218-2100

Attorneys for Amicus Curiae

TABLE OF CONTENTS

Page

Table of Cited Authorities iii

Statement of Interest of *Amicus Curiae* 1

Summary of the Argument 4

Argument 8

I. The Conflict Between The Circuits Raises Serious Practical Problems For Patent Litigants Who Are Considering The Initiation Or Settlement Of Infringement Actions 8

A. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume That Agreements Settling Patent Litigation Remain Favored As A Matter Of Public Policy 8

B. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume The Presumptive Legality Of Patent Settlements Which Are Not "Objectively Baseless" Under The *PRE* Standard 11

Contents

Page

C. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume That The Legality Of Field-Of-Use, Territorial, And Other Conventional Patent License Terms In A Settlement Agreement Will Be Evaluated Under The Rule Of Reason 12

D. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume That A Patentee May Refuse To License A Patent 14

II. The Grant Of Certiorari Would Facilitate Essential Guidance On Settlement Payments For The FTC As Well 15

Conclusion 18

TABLE OF CITED AUTHORITIES

Page

Cases

Abbott Labs., Dkt. No. C-3945 (May 22, 2000) (consent order), (http:www.ftc.gov/os/2000/05/c3945complaint.htm) 16

Advanced Cardiovascular Systems, Inc. v. Medtronic, Inc.,265 F.3d 1294 (Fed. Cir. 2001) 9

Aro Corp. v. Allied Witan Co., 531 F.2d 1368 (6th Cir. 1975) 10

Asahi Glass Co. v. Pentech Pharm., Inc., __ F. Supp. 2d __, 2003 WL 22462405 (N.D. Ill. Oct. 29, 2003) 4

Asberry v. United States Postal Service, 692 F.2d 1378 (Fed. Cir. 1982) 9

Bristol-Myers Squibb, Co. v. Rhone-Poulenc Rorer, Inc., 2002 WL 1733681 (S.D.N.Y. July 26, 2002), *aff'd*, 326 F.3d 1226 (Fed. Cir. 2003) 17

California Dental Ass'n v. FTC, 526 U.S. 756 (1999) 3

Callen v. Pennsylvania R.R. Co, 332 U.S. 625 (1948) 9

Continental T.V. v. GTE Sylvania, 433 U.S. 36 (1977) 3

Evans v. Jeff D., 475 U.S. 717 (1986) 9

Cited Authorities

Page

Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362 (Fed. Cir. 2001) 9

Geneva Pharm., Inc., Dkt. No. C-3946 (May 22, 2000) (consent order), (http://www.ftc.gov/os/2000/05/c3946complaint.htm) 16

Hemstreet v. Spiegel, Inc., 851 F.2d 348 (Fed. Cir. 1988) 9

Hoechst Marion Roussel, Inc., Dkt. No. 9293 (May 8, 2001) (consent order), (http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm) 16

Image Technical Servs. v. Eastman Kodak Co., 125 F.3d 1195 (9th Cir. 1996) 14

In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003), *reh'g denied* (6th Cir. 2003) ... *passim*

In re Independent Serv. Orgs. Antitrust Litig., 203 F.3d 1322 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001) 14, 15

In re Schering-Plough, Appeal Brief of Counsel Supporting the Complaint, at 70-71, FTC Docket No. 9297 (Aug. 9, 2002) (http://www.ftc.gov/os/2002/08/scheringtrialbrief.pdf) 16

Cited Authorities

Page

In re Schering-Plough, Opinion of the Commission, at 8, FTC Docket No. 9297 (Dec. 18, 2003) (http://www.ftc.gov/os/adjpro/d9297 031218final order.pdf) (final order), (http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf) (opinion) 8, 16

Marek v. Chesny, 473 U.S. 1 (1985) 9

Northern Pac. Ry. v. United States, 356 U.S. 1 (1958) 3

Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49 (1993) ..... *passim*

Standard Oil Co. v. United States, 283 U.S. 163 (1931) 8

United States v. Singer Mfg. Co., 374 U.S. 174 (1963) 12

Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003), *reh'g denied* (11th Cir. 2003) ..... *passim*

Walker Process Equip., Inc. v. Food Mach. & Chem. Co., 382 U.S. 172 (1965) 12

Cited Authorities

Page

Statutes

15 U.S.C. § 1 ..... 3, 12

15 U.S.C. § 2 12

15 U.S.C. § 15 15

35 U.S.C. § 261 13

35 U.S.C. § 271(d) 15

35 U.S.C. § 271(d)(4) 14

35 U.S.C. § 271(d)(5) 14

35 U.S.C. § 282 12

Drug Competition Act of 2003, S. REP. No. 108-1 (2003) 17

Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Hatch-Waxman Act) 1

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 (2003) 8

Cited Authorities

Page

Rules

Fed. R. Civ. P. 68 9

Fed. R. Evid. 408 9

Sup. Ct. R. 10(a) 3

Sup. Ct. R. 10(c) 4

Sup. Ct. R. 37.1 5

Sup. Ct. R. 37.2(b) 1

Sup. Ct. R. 37.6 1

Other Authorities

FTC, *Antitrust Guidelines for the Licensing of Intellectual Property* (Apr. 6, 1995) (http://www.usdoj.gov/atr/public/guidelines/ipguide.htm) 12

FTC/DOJ, Public Hearings, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, (2002) (http://www.ftc.gov/opp/intellect/index.htm) 2

G.J. Glover, *Competition in the Pharmaceutical Marketplace*, Testimony before the FTC and the DOJ (March 19, 2002) (http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf) 2

Cited Authorities

Page

William J. Kolasky, DOJ, *Antitrust Compliance Programs: The Government Perspective*, Before the Corporate Compliance 2002 Conference, Practising Law Institute (July 12, 2002) 6

Thomas B. Leary, FTC, *The Dialogue Between Students of Business and Students of Antitrust: A Keynote Address*, Notre Dame Research Workshop and Conference on Marketing, Competitive Conduct and Antitrust Policy (May 3, 2002) ... 5

N.R. Stoll & S. Goldfein, *Patent Protection or Per Se Antitrust Violation?*, New York Law Journal, Nov. 18, 2003 5

STATEMENT OF INTEREST OF *AMICUS CURIAE*

This brief is submitted on behalf of the New York Intellectual Property Law Association ("NYIPLA"), a professional association of more than 1,300 attorneys whose interests and practices lie in the area of patent, copyright, trademark, trade secret and other intellectual property law.[1] NYIPLA members include in-house attorneys working for businesses that own, enforce and challenge patents as well as attorneys in private practice who represent both patent owners and accused infringers. NYIPLA members represent both plaintiffs and defendants in infringement litigation and also regularly participate in proceedings before the United States Patent and Trademark Office ("PTO"), including representation of parties to interferences, as well as representing applicants for patents.

A substantial percentage of NYIPLA members participate actively in patent litigation. Due in part to the concentration of a number of large pharmaceutical firms in the New York metropolitan area, smaller but still quite significant numbers of NYIPLA members participate regularly in litigation involving the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"),[2] as representatives of both segments of the pharmaceutical industry — the traditional research-based "branded" firms as well as their newer "generic" competitors.

---

1. Pursuant to SUP. CT. R. 37.6, the NYIPLA and its counsel represent that they have authored this brief in whole, and that no person or entity other than the *amicus curiae* and its counsel have made a monetary contribution to the preparation or submission of this brief. Pursuant to SUP. CT. R. 37.2(b), a motion for leave is being filed concurrently herewith, since several parties have indicated that they are unable to consent to the filing of this brief.

2. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Both general patent litigators and Hatch-Waxman specialists must remain continuously apprised of the current antitrust ramifications of the initiation and settlement of patent litigation so that their clients can be counseled expeditiously, accurately and effectively. Additionally, to the extent settlements incorporate either patent licenses or refusals to license, the NYIPLA's members must remain conscious of developments regarding the controlling precedents of this Court as interpreted by the federal appellate courts in those related areas as well.

Since its founding in 1922, the NYIPLA has committed itself to maintaining the integrity of United States patent law, and to the proper application of that law. Nowhere is the rational and considered application of patent law principles more important to the economy of the United States than at the interface between those principles and the principles embodied in the antitrust laws.[3] Moreover, in no other industry are the economic stakes surrounding patent protection higher than in the pharmaceutical industry where the average total cost to develop a single new drug is now estimated at $802 million, where the members of the Pharmaceutical Research and Manufacturers of America invested over $30 billion in 2001 alone in discovering and developing new medicines, and where "Average total drug development time has gone from 8.1 years in 1960, to 11.6 years in the 1970s, to 14.2 years in the 1980s and 1990s".[4]

---

3. If there were ever any doubt on that score, it would have been obviated by the testimony given during the lengthy hearings held in early 2002 under the joint sponsorship of the Antitrust Division of the Department of Justice ("DOJ") and the Federal Trade Commission ("FTC"), the agencies charged with enforcement of the antitrust laws. FTC/DOJ, Public Hearings, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, (2002) (http://www.ftc.gov/opp/intellect/index.htm).

4. G.J. Glover, *Competition in the Pharmaceutical Marketplace*, at 1 and 3-4, Testimony before the FTC and the DOJ (March 19, 2002) (http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf).

To further the goal of a properly reasoned and evenly balanced application of both the patent and the antitrust laws, the NYIPLA urges this Court to grant certiorari to obviate an intolerable conflict between two United States courts of appeals under SUP. CT. R. 10(a),[5] and to announce authoritatively whether payments made to an accused patent infringer in connection with the settlement of an infringement action should be evaluated under the rule of reason (as the Eleventh Circuit held in *Valley Drug*), or proscribed as *per se* unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1 (as the Sixth Circuit held in *Cardizem*).

The NYIPLA takes no position at this time on whether the rule of reason should control or whether, to the contrary, the case should be treated under the standards set forth in this Court's previous articulations of the circumstances under which *per se* treatment of a restraint would be appropriate.[6] As Petitioners have pointed out (Pet. Br. at 25), it "has historically been the role and function of the Supreme Court" to promulgate guidelines for those situations in which the rule of reason should be abandoned in favor of a *per se* rule.[7]

---

5. *Compare In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *reh'g denied* (6th Cir. 2003) ("*Cardizem*"), *with Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *reh'g denied* (11th Cir. 2003) ("*Valley Drug*"). For the convenience of the Court, references to the *Cardizem* and *Valley Drug* decisions herein are made by citation both to the official reporter and to Petitioners Appendix in the form "Pet. App. at __". References to Petitioners Brief herein are in the form "Pet. Br. at __".

6. *Northern Pac. Ry. v. United States*, 356 U.S. 1, 5 (1958) (*per se* rule appropriate where challenged restraint lacks "any redeeming virtue"); *California Dental Ass'n v. FTC*, 526 U.S. 756, 778 (1999) (or "plausible procompetitive benefit").

7. *Citing Continental T.V. v. GTE Sylvania*, 433 U.S. 36, 49-50 (1977).

Additionally, the NYIPLA respectfully submits that the Sixth Circuit's *Cardizem* decision would seem to raise issues under a number of this Court's previous decisions.[8] The NYIPLA makes no claim that the Sixth Circuit's *Cardizem* decision directly "conflicts with relevant decisions of this Court" under SUP. CT. R. 10(c).[9] However, if this Court should rule that "reverse" or "exit" settlement payments should be deemed *per se* unlawful, it would seem that some guidance regarding the continuing vitality of *PRE* and a number of this Court's other precedents regulating conduct at the antitrust-intellectual property interface also would be warranted.[10]

SUMMARY OF THE ARGUMENT

The nature of the stark conflict between the Sixth Circuit's *Cardizem* decision and the Eleventh Circuit's ruling in *Valley*

---

8. *E.g., Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (setting forth the standards governing when the presumption of validity and good faith initiation of intellectual property litigation can be overcome) ("*PRE*"). Patent litigation practitioners have been advising their clients for almost ten years that the *PRE* standards are just as applicable to the settlement of patent litigation as to its initiation. Indeed, Judge Posner's recognition of this principle in *Asahi Glass Co. v. Pentech Pharm., Inc.*, __ F. Supp. 2d __, 2003 WL 22462405 (N.D. Ill. Oct. 29, 2003) ("*Asahi*"), represented a key theoretical underpinning for his criticism of the Sixth Circuit's *Cardizem* decision.

9. The NYIPLA nevertheless does believe that the Sixth Circuit's *Cardizem* decision "has decided an important question of federal law that has not been, but should be, settled by this Court" within the meaning of Rule 10(c).

10. As developed in Point I of the argument, the *Cardizem* decision calls into question no less than four separate touchstone principles, all derived from the decisions of this Court as interpreted by the United States courts of appeals, upon which counselors have come to rely in advising their clients on patent litigation settlements and related matters.

Drug is dealt with cogently and thoroughly in Point I of Petitioner's brief (Pet. Br. at 9-12),[11] and no further discussion of that conflict seems appropriate here.[12]

Point I

Point I of this brief discusses the confusion and potential for serious inconsistency faced by NYIPLA members as they struggle to counsel their clients while the conflict remains unresolved.[13] This focus on the practitioner's counseling role seems particularly appropriate in this field where representatives of both the DOJ and FTC enforcement agencies have repeatedly stressed the primary role of the private and corporate bars in securing and maintaining antitrust compliance.[14]

---

11. In a recent article, two New York antitrust practitioners analogized this "notorious split" between the Sixth and Eleventh Circuits to "a storm" in "the antitrust world" and speculated that in order to "calm the fury", this Court might be prompted to examine whether settlement payments are "so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality". N.R. Stoll & S. Goldfein, *Patent Protection or Per Se Antitrust Violation?*, New York Law Journal, Nov. 18, 2003, at 3, *citing National Society of Professional Engineers v. United States*, 435 U.S. 679, 692 (1978).

12. The NYIPLA is mindful of this Court's directive that a brief for *amicus curiae* should be limited to "relevant matter not already brought to its attention by the parties" (SUP. CT. R. 37.1).

13. Point II of Petitioner's brief discusses the different but parallel confusion and potential for serious inconsistency in the lower federal courts absent the grant of certiorari and resolution of the conflict by this Court (Pet. Br. at 12-19).

14. *See, e.g.*, Thomas B. Leary, FTC, *The Dialogue Between Students of Business and Students of Antitrust: A Keynote Address*, Notre Dame Research Workshop and Conference on Marketing, Competitive Conduct and Antitrust Policy, at 4, (May 3, 2002) ("The people who (Cont'd)

Patent litigators and counselors have heretofore employed four separate touchstone principles in advising their clients on patent settlements and licenses: —

– First, because agreements settling patent litigation remain favored as a matter of public policy, the antitrust legality of their ancillary or subsidiary terms should be evaluated under the rule of reason rather than as naked horizontal restraints (Point I.A);

– Second, patent settlement agreements remain presumptively lawful unless and until proved to be "objectively baseless" under the standard announced by this Court in *PRE* (Point I.B);

– Third, because territorial and field of use market allocations represent lawful ancillary restraints in a patent license, a temporal restriction on entry can be justified *a fortiori* as representing nothing more than a promise not to infringe for all or a portion of a presumptively valid patent's remaining term (Point I.C); and

– Finally, a patentee's refusal to license is always justifiable as part of what the Solicitor General recently told this Court represented "the core patent right of exclusion" (Point I.D).

Each of the four touchstone principles is grounded in the prior decisions of this Court as interpreted by the federal

---

(Cont'd)
really enforce the antitrust laws, day-to-day, are private counselors employed either as 'inside' or 'outside' lawyers."); William J. Kolasky, DOJ, *Antitrust Compliance Programs: The Government Perspective*, Before the Corporate Compliance 2002 Conference, Practising Law Institute (July 12, 2002).

appellate courts – for the last twenty years, perhaps most prominently by the Court of Appeals for the Federal Circuit.[15] In each of the four areas, the Sixth Circuit's *Cardizem* decision failed to indicate how a *per se* rule proscribing settlement payments could be accommodated with those precedents. Should the Court opt for a *per se* proscription of settlement payments, guidance will be required regarding the continuing vitality of the precedents upon which litigators at the interface have long been basing their advice.

Point II

The grant of certiorari here would facilitate essential guidance not only for the lower federal courts and for those who counsel the litigants therein, but also for the FTC. Two very recent developments highlight the prominent role that the FTC has assumed in evaluating the antitrust legality of patent settlement payments and suggest that timely guidance is warranted because this role may soon be greatly expanded.

First, on December 18, 2003, the FTC reversed the dismissal of a complaint by the Administrative Law Judge ("ALJ") and held both (a) that Complaint Counsel had discharged their initial burden of establishing that at least part of the payments made by a patentee to two ANDA filers under settlement agreements had been made in return for promises to defer generic entry to dates certain in advance of the expiration of the asserted patent, and (b) that the Respondent had failed to "demonstrate that the challenged

---

15. Because of the Congressional mandate for uniformity in patent law which led to its creation, the regional federal courts of appeals have often deferred to the expertise of the Court of Appeals for the Federal Circuit in matters concerning the interface between patent law and antitrust.

provisions are justified by procompetitive benefits that are both cognizable and plausible".[16]

Second, on December 8, 2003, just ten days before the FTC issued its ruling in *Schering-Plough*, the President signed into law the "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" ("Medicare Act"), the filing requirements of which make it virtually certain that the FTC staff will soon assume an even greater role in policing and challenging settlement payments.[17]

ARGUMENT

I. THE CONFLICT BETWEEN THE CIRCUITS RAISES SERIOUS PRACTICAL PROBLEMS FOR PATENT LITIGANTS WHO ARE CONSIDERING THE INITIATION OR SETTLEMENT OF INFRINGEMENT ACTIONS

A. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume That Agreements Settling Patent Litigation Remain Favored As A Matter Of Public Policy

In the more than seventy years that have elapsed since the decision in *Gasoline Cracking*,[18] patent litigators have remained confident that this Court would continue to evaluate the terms of patent dispute settlements between potential competitors as

---

16. *In re Schering-Plough*, Opinion of the Commission, at 8, FTC Docket No. 9297 (Dec. 18, 2003) ("*Schering-Plough*") (http://www.ftc.gov/os/adjpro/d9297/031218finalorder.pdf) (final order), (http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf) (opinion).

17. Pub. L. No. 108-173 (2003).

18. *Standard Oil Co. v. United States*, 283 U.S. 163 (1931).

ancillary or subsidiary terms under the rule of reason rather than as naked horizontal restraints. Frequent references in the decisions of this Court and the federal appellate courts to the strong public policy favoring the settlement of litigation in general and patent litigation in particular have buttressed this confidence. *E.g.*, *Callen v. Pennsylvania R.R. Co*, 332 U.S. 625, 630 (1948); *Asberry v. United States Postal Service*, 692 F.2d 1378 (Fed. Cir. 1982); *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350 (Fed. Cir. 1988); *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369-70 (Fed. Cir. 2001).

The public policy favoring the settlement of litigation so pervades the fabric of federal law that provisions of both the Federal Rules of Civil Procedure and the Federal Rules of Evidence have been tailored specifically to reflect that policy. *See Advanced Cardiovascular Systems, Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1308 (Fed. Cir. 2001) (Fed. R. Evid. 408); *Marek v. Chesny*, 473 U.S. 1, 5 (1985) (Fed. R. Civ. P. 68).[19]

---

19. In *Marek v. Chesny*, 473 U.S. at 5, this Court explained:

> The plain purpose of Rule 68 is to encourage settlement and avoid litigation. The Rule prompts both parties to a suit to evaluate the risks and costs of litigation, and to balance them against the likelihood of success upon trial on the merits.

(*citing Advisory Committee Note on Rules of Civil Procedure, Report of Proposed Amendments*, 5 F.R.D. 433, 483 n. 1 (1946), 28 U.S.C.App., p. 637). This Court went on to note that:

> Rule 68's policy of encouraging settlements is neutral, favoring neither plaintiffs nor defendants; it expresses a clear policy of favoring settlement of *all* lawsuits.

Id. at 10, (emphasis supplied). *See also*, *Evans v. Jeff D.*, 475 U.S. 717, 733 (1986) ("In approving the package offer in *Marek v. Chesny* we recognized that a rule prohibiting the comprehensive negotiation of all outstanding issues in a pending case might well preclude the settlement of a substantial number of cases: . . .").

The Court of Appeals for the Sixth Circuit cogently summarized the principle in *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1975), an opinion written by then Chief Judge Markey of the Court of Customs and Patent Appeals sitting by designation, where the Court said:

> Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. Settlement agreements should therefore be upheld whenever equitable and policy considerations so permit. By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes support the latter.

In *Cardizem*, however, the Sixth Circuit made no mention whatsoever of either the public policy favoring settlements, or its own prior decisions setting forth that principle. If public policy favors settlement agreements, their terms should be evaluated under a standard that encourages the parties to settle. Since application of the *per se* rule to settlement payments appears inconsistent with the public policy favoring settlement of patent litigation, clarification by this Court is required.

B. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume The Presumptive Legality Of Patent Settlements Which Are Not "Objectively Baseless" Under The *PRE* Standard

As mentioned in passing, *supra*, the Sixth Circuit's decision in *Cardizem* also failed to consider the effect of this Court's ruling in *PRE* that before initiation of an intellectual property lawsuit can be proscribed under the antitrust laws a two-part test must be satisfied:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits . . . Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation . . . This two-tiered process requires the plaintiff to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability.

508 U.S. at 60-61 (emphasis in original).

Since initiation of a patent infringement action must be presumed legitimate unless and until proved to be "objectively baseless", settlement of such an action likewise must be presumed to represent a legitimate promise to forbear from further asserting valid patent claims against the accused infringer unless and until proved otherwise. Thus, even if a patent settlement results in the accused infringer remaining out of the marketplace until expiration of the patent, it must be presumed that the same result would have been achieved in the lawsuit by virtue of the presumptively valid patent.

Under the logic of *PRE*, therefore, it would seem that any challenge to a term of a settlement agreement would have to proceed under the rule of reason unless and until the challenger could demonstrate by objective evidence that legitimate entry would have occurred in spite of the patent — usually for reasons of invalidity or non-infringement.[20] The Sixth Circuit in *Cardizem* failed to consider whether a *per se* rule that assumes an anticompetitive effect would conflict with both the reasoning of *PRE* and the principle that patent claims must be presumed valid.[21]

C. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume That The Legality Of Field-Of-Use, Territorial, And Other Conventional Patent License Terms In A Settlement Agreement Will Be Evaluated Under The Rule Of Reason

The enforcement agencies concede that intellectual property licensing "is generally procompetitive",[22] often "can facilitate

---

20. There are, of course, situations where a settlement agreement could run afoul of the *PRE* standard without any formal showing of invalidity or non-infringement. For example, where the accused infringer becomes privy to clearly invalidating evidence, the *PRE* standard could be satisfied and the putative settlement agreement itself could be attacked under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2. *See United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963). Additionally, the accused infringer could ascertain during discovery that the patent at issue had clearly been procured by fraud upon the PTO. Once again, the *PRE* standard could be satisfied by such a showing, and the "sham" settlement could be attacked under Sherman Act Sections 1and 2 under the authority of *Walker Process Equip., Inc. v. Food Mach. & Chem. Co.*, 382 U.S. 172 (1965).

21. 35 U.S.C. § 282.

22. FTC, *Antitrust Guidelines for the Licensing of Intellectual Property*, at 3 (Apr. 6, 1995), ("Licensing Guidelines") (http://www.usdoj.gov/atr/public/guidelines/ipguide.htm).

integration of the licensed property with complementary factors of production",[23] and in "the vast majority of cases" should be "evaluated under the rule of reason".[24] Thus, "Field-of-use, territorial, and other limitations on intellectual property licenses may serve procompetitive ends by allowing the licensor to exploit its property as efficiently and effectively as possible". Licensing Guidelines at 6. Proscription under a *per se* rule is reserved for those restraints which, under the decisions of this Court as interpreted by the federal courts of appeals: "merit *per se* treatment, including price fixing, allocation of markets or customers, agreements to reduce output, and certain group boycotts". *Id.* at 23.

The Sixth Circuit in *Cardizem* concluded that an agreement not to infringe a presumptively valid patent by entering the market before an agreed date could be characterized as a *per se* unlawful "horizontal agreement to eliminate competition in the market". *In re Cardizem*, 332 F.3d 896, 908 (6th Cir. 2003) (Pet. App. at 18a). It did so based upon a review limited to this Court's non-patent decisions explaining application of the *per se* rule (Pet. App. at 15a-17a). Moreover, the Sixth Circuit provided no rationale for distinguishing between, on the one hand, the proscribed temporal market allocation represented by the delayed entry of the generic and, on the other hand, the field of use and territorial market allocations which the FTC and DOJ have indicated are presumptively lawful.[25]

---

23. *Id.* at 5.

24. *Id.* at 15.

25. Indeed, to the extent the Sixth Circuit in *Cardizem* may have equated "market allocation" with "naked horizontal restraints pertaining to . . . territories", it also ignored both 35 U.S.C. § 261 and the policy determinations of the DOJ and FTC as reflected in the Licensing Guidelines.

If this Court should determine that a *per se* analysis of settlement payments is appropriate, care should be taken that the announced rule does not extend to practices like territorial and field-of-use limitations which, unlike price fixing, the enforcement agencies agree should be assessed under the rule of reason.

D. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume That A Patentee May Refuse To License A Patent

In *Xerox (ISO)*, the Federal Circuit found "support" for the patentee's right to refuse to license with impunity in Congressional enactment of Section 271(d)(4) of the Patent Code.[26] The Federal Circuit concluded that, to the extent Section 271(d)(4) defines conduct that cannot support unenforceability, such a determination *a fortiori* should preclude any attempt to ground an antitrust violation upon the same conduct. While the Solicitor General's brief in this Court recommending against the grant of certiorari stopped short of directly endorsing that reasoning, the Solicitor General did concede that even the Ninth Circuit in *Kodak II* reads Section 271(d)(4) to "indicate congressional intent to protect the core patent right of exclusion" (Br. at 12 n.6).[27] The Federal Circuit also

---

26. *In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001). ("*Xerox (ISO)*").

27. *Image Technical Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1215 (9th Cir. 1996). Indeed, Congress included "market power" as a necessary element for removing a tying arrangement from the safe harbor of Section 271(d)(5) and failed to do the same for Section 271(d)(4). This suggests strongly that Congress intended refusals to license to remain permissible even where the exclusionary power of a patent claim can be shown to be coextensive with some economically significant relevant market.

extended the rule of *PRE* to the alleged Section 2 claim in *Xerox (ISO)*.[28]

The Sixth Circuit would have required only a slight extension of its logic in *Cardizem* to have held additionally that the "horizontal agreement to eliminate competition" was tantamount to a refusal to license during the period before delayed entry. To ameliorate the acute problems of interpretation that the patent community faces, should this Court determine that settlement payments should be tested under a *per se* rule, guidance should be provided as to whether the scope of that ruling extends as well to any aspect of 35 U.S.C. § 271(d).

II. THE GRANT OF CERTIORARI WOULD FACILITATE ESSENTIAL GUIDANCE ON SETTLEMENT PAYMENTS FOR THE FTC AS WELL

Although the FTC is not a party to the *Cardizem* action, its publication of an administrative FTC complaint prompted the actions later consolidated into the multidistrict proceeding in which the Sixth Circuit rendered its decision.[29] Moreover, the

---

28. *In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d at 1327-28. Irrespective of what particular constitutional provisions are deemed to support the *PRE* rule, it seems unfair to burden a jury with the task of differentiating between situations where a patentee's refusal to deal involves the presumptively legitimate purpose of "protection of intellectual property" and those where the purpose for the very same refusal is merely "pretextual". The Ninth Circuit's ruling in *Kodak II* clearly asked too much of the jury — particularly where it was necessary to find an erroneous instruction "harmless error" in order to sustain an $80 million verdict.

29. Indeed, this is a common pattern. In every instance where the FTC has challenged a settlement payment made in connection with the termination of an ANDA infringement action, purchaser classes and other treble damages plaintiffs subsequently have sought recovery under Section 4 of the Clayton Act, 15 U.S.C. § 15 — even where the

(Cont'd)

FTC staff has often argued that ANDA settlement payments are *per se* illegal.[30]

Commissioner Leary's opinion in *Schering-Plough*, published on December 18, 2003, demonstrated full awareness of the conflict between the Sixth and Eleventh Circuits. While rejecting application of the *per se* rule of *Cardizem* and purporting to employ "a properly structured rule-of-reason inquiry" (Slip Op. at 87), the decision stopped well short of the full rule of reason inquiry used by the Eleventh Circuit in *Valley Drug*. Indeed, the FTC's order prohibits prospective settlements of ANDA litigation in which the generic "receives anything of value" other than payments "linked to litigation costs, up to $2 million, and for which the Commission has been notified of the settlement" (*Id.* at 88).

By prohibiting future settlement payments in excess of $2 million, the Commission has apparently signaled that it will no longer countenance payments in excess of that maximum even where such payments are commensurate with "expected litigation costs" as a recent consent settlement had permitted.[31] This seemingly arbitrary posture may represent the product of the Commission's apparent skepticism regarding the magnitude

(Cont'd)
matter was promptly disposed of upon consent. *See Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), *complaint available at* (http:www.ftc.gov/os/2000/05/c3945complaint.htm); *Geneva Pharm., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), *complaint available at* (http://www.ftc.gov/os/2000/05/c3946complaint.htm); *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), *complaint available at* (http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm).

30. *E.g.*, *In re Schering-Plough*, Opinion of the Commission, at 12, *citing* App. Br. at 70-71.

31. *Id.* at 37, citing *Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076, *available at* (http://www.ftc.gov/os/2003/03/bristolmyersdo.pdf).

of actual litigation costs.[32] Actual legal fees in patent litigation, however, sometimes can exceed $25 million.[33]

The Commission's order in *Schering-Plough* probably foreshadows the treatment that the industry can expect for ANDA settlement agreements under the Medicare Act amendment of December 8, 2003. Title XI, Subtitle B, Sec. 1112(c)(1) of that Act requires that each brand name and generic drug company entering into an ANDA agreement shall "file with the Assistant Attorney General and the Commission the text of any such agreement". Under Title IX, Sec. 903 of the "Drug Competition Act of 2003",[34] the purposes of the Act are (1) to provide timely notice to the DOJ and the FTC of agreements between companies who market patented proprietary drugs and generics and (2) to thereby enhance the enforcement of the antitrust and competition law of the United States.

Absent guidance from this Court, Hatch-Waxman litigants who wish to settle apparently will be faced with the choice of either settling on terms that the FTC will accept or risk FTC challenge to their settlements — with the daunting prospect of the private treble damages litigation under the Clayton Act, which inevitably follows any such challenge.

---

32. *Id.* at 82, characterizing a payment of $5 million, although "ostensibly" for legal fees, as "probably well in excess of AHP's attorneys fees".

33. *See Bristol-Myers Squibb, Co. v. Rhone-Poulenc Rorer, Inc.*, 2002 WL 1733681 (S.D.N.Y. July 26, 2002), *aff'd*, 326 F.3d 1226 (Fed. Cir. 2003).

34. S. REP. NO. 108-1 (2003).

CONCLUSION

For all the foregoing reasons, the NYIPLA respectfully submits that this Court should grant certiorari to obviate an intolerable conflict between two United States courts of appeals and announce authoritatively whether payments made to an accused infringer in connection with the settlement of an infringement action should be evaluated under the rule of reason (as the Eleventh Circuit held in *Valley Drug*), or proscribed as *per se* unlawful under Section 1 of the Sherman Act (as the Sixth Circuit held in *Cardizem*). The expeditious resolution of this conflict is of critical importance for the entire patent community, because the potential ripple effect of *Cardizem* could affect application of any number of related principles upon which that community has long relied. Indeed, with the filing requirements of the Medicare Act now looming on the horizon, it is also of critical importance to the patent community that the FTC should obtain the authoritative guidance of this Court as well.

Respectfully submitted,

MELVIN C. GARNER, PRESIDENT
DARBY & DARBY, PC
805 Third Avenue
New York, NY 10022
(212) 527-7717

DAVID F. RYAN
Counsel of Record
MATTHEW S. SEIDNER
FITZPATRICK, CELLA,
HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112
(212) 218-2100

Attorneys for Amicus Curiae